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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/060,047	04/14/1998	RICHARD L. DUNN	8905.157US01	9184

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10/14/2004

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE

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09/060047

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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9/18/04

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7/6/04

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-3, 14, 15, 19, 28-32 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-3, 14, 15, 19, 28-32 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 8/16/04
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1617

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 14-15, 19, 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al.

Yamamoto et al teach a W/O emulsion composed of a water soluble drug containing solution as the inner aqueous phase and a polymer containing solution as the oil phase (abstract). Polylactic acid is disclosed (column 5 line 2). Ethyl acetate is specified (column 5 lines 58-59). Antiflammatory agents are disclosed (column 3 lines 21-22). A polymer concentration up to 80% is specified (column 6, lines 58-61). Starch is disclosed (column 4 line 41). The examiner takes Judicial notice under MPEP 2144.03 that starch is well-known in the art as an ^Cexpedient_A. The examiner notes that in Yamamoto et al, the drug retaining substance is optional (column 4 lines 17-20).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 14, 15, 19, 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al.

Okada et al teach water-oil emulsions comprising a water-soluble drug in the aqueous phase and a polymer in the oil phase (abstract). Anti-flammatory drugs are

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specified (column 1 line 45). Polylactic acid is disclosed (column 5, lines 1-5). ^A concentration of polymer up to 90% (w/w) is specified (column 5, lines 46-48). Ethyl acetate is disclosed (column 5 line 57). An intended ^{use} is not considered a patentable _Λ limitation during prosecution before the USPTO. Starch is disclosed as a drug retaining substance (column 4 lines 11-22, 33). The examiner takes notice under MPEP that starch is a well-known expedient, that is, an inert carrier for a drug. Applicant argues "consisting essentially of" overcomes the rejection. However he now claims an ^c expedient in the aqueous medium. _Λ

Claims 28, 32 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 28, 32 broaden rather than limit claim 1 ^{by} ~~by~~ adding additional essential ingredients to the composition.

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Nowhere in the specification or original claims does applicant disclose a mixture of polymers and non-polymeric material in the organic phase. They are disclosed only in the alternative.

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Claim 28 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for lipids, does not reasonably provide enablement for any non-polymeric material, such as a salt. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. On page 20 lines 21 et SEQ. applicants recite a list of substantially water-insoluble compounds that may broadly be characterized as lipids. No other class of compounds is specified.

No claims allowed.

The prior recited on the PTO form 1449 supplied with the remarks filed 7/6/04 is not of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (571) 272-0633. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Webman/LR
September 21, 2004

